

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS. 4641-4660**

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium, and its strength differed from, or its quality or purity fell below, the standard set forth in such compendium; and, Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in its labeling.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER
WHEN USED ACCORDING TO DIRECTIONS**

4641. Dr. Reilly's Applicator and Dilator Assembly (a device) and Dr. Reilly's Rectal Remedy Pile-Aid (a drug). (Inj. No. 272.)

COMPLAINT FOR INJUNCTION FILED: 1-7-54, E. Dist. Wis., against Dr. Reilly's, Inc., Milwaukee, Wis., and its president, Dr. John F. Reilly; and Hunter Enterprises, Inc., Milwaukee, Wis., and its president, Robert S. Hunter, to enjoin the interstate shipment of the above-mentioned drug and device, which were misbranded.

ACCOMPANYING LABELING: Testimonial letters dated 4-15-52 and 6-30-52 signed by Evelyn Donner and Edward R. Hoffmann, a form letter addressed to "Dear Friend" and beginning with the words "I am not only sending," a leaflet entitled "Important Information Direct from Dr. Reilly," a leaflet entitled "Dr. Reilly's Medicating Applicator," a leaflet headed "This Concerns Your Health," a form letter addressed to "Dear Friend" and beginning with the words "Until now no easy, convenient, inexpensive home treatment has been available," a form letter addressed to "Dear Friend" and beginning with the words "You will find enclosed answers to questions sometimes asked," a pamphlet entitled "Comfort for all the family," and a leaflet containing "Instructions for Use."

RESULTS OF INVESTIGATION: The device consisted essentially of a small metal pump, plastic tubing, a plastic applicator, and rectal dilators, and was designed to be attached to a bottle of the drug and to inject the drug into the rectum.

The drug consisted of a solution of camphor-phenol in mineral oil, together with a small amount of a certified coal-tar color. The drug was packaged in 8-ounce bottles suitable for attachment to the device.

CHARGE: The complaint alleged that the defendants had been and still were engaged in the business of distributing, selling, and introducing into interstate commerce the above-mentioned drug and device, which were misbranded as follows:

502 (a)—the labeling contained false and misleading representations that the articles, when used in combination, constituted an adequate and effective remedy for piles, hemorrhoids, rectal irritations, inflamed tissue,

spastic rectum, rectal fistula, rectal fissure, rectal bleeding, lower colon troubles, swollen rectal protrusions, and rectal soreness; that the articles, when used in combination, would restore normal elimination desire (regularity) and normal conditions, would re-establish rectal health, and would reduce the possibility of rectal cancer; and that the article of device was safe;

502 (f) (1)—the labeling of the device failed to bear adequate directions for use for the purposes for which it was intended;

502 (j)—the device was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in an accompanying circular containing "Instructions for Use."

DISPOSITION: On 1-7-54, a temporary restraining order was entered against the defendants enjoining them against the acts complained of, and on 1-22-54, a preliminary injunction was entered. Thereafter, on 9-3-54, with the consent of the defendants, a decree of permanent injunction was entered enjoining the defendants against introducing into interstate commerce the device and drug involved, or any similar article of device and drug, which were misbranded as alleged in the complaint.

In addition, the decree stated that nothing in the injunction should prevent the defendants from introducing into interstate commerce the ointment designated as "Dr. Reilly's Rectal Remedy and Pile-Aid," under suitable labeling, for use for the temporary relief of itching and irritation associated with hemorrhoids, provided that a new name is adopted for such ointment which does not create the false and misleading impression that the ointment is of value in the treatment or cure of hemorrhoids, and provided further that no labeling statements, collateral literature, or advertising material is used which represents or suggests that the ointment is of value in the treatment or cure of hemorrhoids.

The decree stated also that the defendants could ship the device in interstate commerce to licensed physicians, hospitals, and clinics for professional use and to persons lawfully engaged in the storage or wholesale or retail distribution of medical devices for sale on the prescription of a physician, provided the label on the device stated the method of its application or use and bore the statement "Caution: Federal law restricts this device to sale by or on the order of a physician," and that there was made readily available to physicians licensed by law to use or order the use of the device brochures bearing information concerning the use of the device.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4642. Tryptacin tablets (47 seizure actions). (F. D. C. Nos. 35667, 35669, 35670, 35679, 35682/6, 35690, 35693, 35695, 35703, 35709/12, 35715, 35721, 35725, 35726, 35728, 35729, 36022/5, 36030/3, 36035/8, 36041/3, 36045/53, 36055, 36056, 36067, 36068, 36073, 36091/3. S. Nos. 14-743 L, 17-595 L, 19-848 L, 20-097/9 L, 20-104 L, 20-110 L, 35-520/1 L, 35-527/8 L, 39-554 L, 39-562 L, 42-630 L, 42-891/3 L, 43-163 L, 43-165/6 L, 43-169/70 L, 43-313/4 L, 47-921 L, 48-106/7 L, 58-253/5 L, 58-257 L, 58-260/2 L, 59-184/5 L, 59-392/6 L, 64-364 L, 65-375/6 L, 70-052 L, 72-361 L, 73-888/90 L, 75-976 L, 83-473/4 L, 83-477 L, 83-481 L, 83-855 L.)

*See also No. 4641.